UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MIRIAM BIRDSONG and CHERYL MIKEL, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

WALGREENS, INC.,

Defendant.

No. 24-cv-07994

Judge Thomas M. Durkin

MEMORANDUM OPINION AND ORDER

Plaintiffs allege that Walgreens sold them over-the-counter medicine containing benzene without warning them of that risk. Walgreens moves to dismiss for lack of standing and failure to state a claim pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). *See* R. 14. That motion is granted.

Background

The medicine Plaintiffs purchased from Walgreens provided mucus relief with an extended release. Medicine can be made to have an extended release effect with an ingredient called "carbomer." Some carbomers are produced using benzene as a solvent. This can result in traces of benzene remaining in the carbomer and then in the medicine itself.

Plaintiffs allege that the mucus relief medicine Walgreens sells under its generic brand includes a carbomer produced using benzene. On this basis, Plaintiffs allege that Walgreens's mucus relief medicine contains benzene. They claim that Walgreens should have disclosed to cosumers that its mucus relief medicine contains

benzene. They claim that Walgreens' failure to disclose this information violates various state statutes and tort law.

Analysis

Walgreens makes several arguments that Plaintiffs' claims should be dismissed. The Court needs only to address the first two—standing and preemption—to dispose of the motion.

I. Standing

Walgreens contends that it sells several different mucus medications, which are made by several different manufacturers, not all of which use carbomer produced with benzene. On this basis, Walgreens argues that Plaintiffs have not plausibly alleged they have standing because they have not specifically alleged which Walgreens product they purchased and whether it is one of the products that contains benzene.

The problem with Walgreens' argument is that these facts about Walgreens' mucus medications are *not* contained in the complaint. The complaint does not allege that some Walgreens mucus medication contains benzene and some doesn't. Rather, Plaintiffs expressly allege that *all* "the generic versions of Mucinex sold by Defendant Walgreens uses benzene containing components for its extended-release effect," such that *all* Walgrees mucus medications "are contaminated with . . . benzene." R. 5 at 2 (¶¶ 3, 6).

While that might not be true, and it might not be true for the reasons Walgreens has identified on this motion, Walgreens's dispute of the factual assertions

in the complaint doesn't make them implausible. Notably, Walgreens appears to admit in its brief that some of its mucus medication is produced with carbomer that is produced with benzene. *See* R. 14 at 3 ("at least one of the manufacturers that makes the Products uses a carbomer that is permitted to contain benzene"). Discovery is necessary to determine whether the Plaintiffs bought one of the Walgreens medicines that contains benzene.

This case is different from those cited by Walgreens, in which the allegations in the complaint distinguished between products that were contaminated and those that were not. *See In re Recalled Abbott Infant Formula Prods. Liab. Litig.*, 2023 WL 3585759, at *4 (N.D. Ill. May 22, 2023) (dismissing plaintiffs who had "not alleged any facts regarding the percentage of products or lots sold by Abbott that were contaminated"); *Huertas v. Bayer US LLC*, 120 F.4th 1169, 1181 (3d Cir. 2024) (affirming dismissal of plaintiffs who failed to allege they purchased from a specific lot that was recalled and tested positive for contamination). In those cases, the courts dismissed for lack of standing because the plaintiffs were not able to plausibly allege that they had purchased a contaminated product in the face of their admissions that a high percentage of the defendants' products were not contaminated. Walgreens identifies facts that create an analogy to those other cases. But as discussed, none of those facts are alleged in Plaintiffs' complaint in this case. Discovery might reveal that Plaintiffs cannot show they purchased medicine containing benzene. But their allegations that they did so are plausible, and so Plaintiffs' claims should not be dismissed for lack of standing.

II. Preemption

The Food, Drug, and Cosmetic Act ("FDCA") expressly preempts any claim under state law that "relate[s] to the regulation of [an over-the-counter drug]" and that imposes a requirement on the manufacturer that "is different from or in addition to, or that is otherwise not identical with, a requirement under [relevant federal law]." 21 U.S.C. § 379r(a). Plaintiffs' claims, which are made under state law, are based on the allegation that Walgreens "didn't notify Plaintiffs . . . of the . . . risk of Benzene through the product labels, instructions, ingredients list, other packaging, advertising, or in any other manner." R. 5 at 3 (¶ 14). For Plaintiffs' claims to survive preemption, Walgreens' failure to disclosure the risk of benzene in its mucus medication must plausibly violate a federal requirement. *See Barnes v. Unilever United States Inc.*, 2023 WL 2456385, at *5 (N.D. Ill. Mar. 11, 2023) (citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) (the preemption provision "protects a . . . manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law") (emphases in original)); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005) ("[A] state cause of action that seeks to enforce a federal requirement does not impose a requirement that is 'different from, or in addition to,' requirements under federal law.")).

A. Label Requirements

To the extent Plaintiffs claim that Walgreens was required to include benzene as an ingredient on the labels of its various mucus medication products, that claim is

preempted. The FDCA provides that only "active ingredients" and "inactive ingredients" may be listed on the labeling. *See* 21 U.S.C. § 352(e); 21 C.F.R. § 201.66. An "active ingredient" is "any component that is *intended* to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or any function of the body of humans." 21 C.F.R. § 201.66(b)(2) (emphasis added). An "inactive ingredient" is any "component" that is not an active ingredient. *Id.* § 201.66(b)(8). A "component" is "any ingredient *intended* for use in the manufacture of a [finished] drug product, including those that may not appear in such drug product." *Id.* § 210.3(b)(3) (emphasis added). "Accordingly, FDA regulations require [manufacturers] to list only 'ingredient[s] intended for use' in its products, not unintended contaminants such as benzene." *Barnes v. Unilever United States Inc.*, 2023 WL 2456385, at *7 (N.D. Ill. Mar. 11, 2023) (citing *Truss v. Bayer Healthcare Pharms. Inc.*, 2022 WL 16951538, at *4 (S.D.N.Y. Nov. 15, 2022)). Plaintiffs do not allege that Walgreens or any manufacturer *intends* for benzene to be present in the mucus medication, only that the manufacturers use a carbomer that was manufactured with benzene. Because benzene is not an "intended" component, it is neither an active nor inactive ingredient, and so the FDCA prohibits its inclusion in labeling. And because the FDCA prohibits inclusion of benzene in the label as an ingredient, Plaintiffs' claims that state law requires its inclusion are preempted.

B. Safety Misrepresentations

Plaintiffs also argue, however, that even if the FDCA preempts their claim about benzene being omitted from the label, the FDCA does not preempt its alternative claim that Walgreens made "affirmative misrepresentations about product safety" in its marketing. *See* R. 23 at 9. Plaintiffs cite *Barnes* in which the court found that state law claims based on alleged affirmative misrepresentations in marketing were not preempted by the FDCA. *See* 2023 WL 2456385, at *10 ("deceptive practices claims based on alleged affirmative misrepresentations . . . are not preempted").

This problem with this argument is that Plaintiffs do not allege that Walgreens made any affirmative misrepresentations that are not based in Walgreens's failure to disclose the presence of benzene in its mucus medications. Plaintiffs allege that "[t]hrough marketing and sale, [Walgreens] represented that [its mucus medication products] are safe for people, including pregnant women and their newborns, adults aged 65 or older, and people with weakened immune systems." R. 5 at 3 (¶ 12). Standing alone, this is an allegation of an affirmative representation regarding the safety of the medications. But the basis for Plaintiffs to claim that the representation is false is the next paragraph in the complaint which states: "Plaintiffs and consumers do not know, and did not have a reason to know, that [the mucus medication products they] purchased were contaminated with Benzene. Consumers expect the products they purchase to be safe for use and not contaminated by Benzene, which can cause cancer." *Id.* (¶ 13). In other words, Plaintiffs' allegation that Walgreens

misrepresented the safety of its mucus medication is not factually different from their claim that Walgreens should have disclosed the presence of benzene in the medication.

But as discussed, the FDCA does not require Walgreens to disclose the presence of benzene in its mucus medication, even when it contains a carbomer produced using benzene. Without claiming that the FDCA required Walgreens to disclose the risk of benzene in the medicine, a finding that Walgreens was required to warn Plaintiffs of the risk of benzene would effectively impose a duty of Walgreens regarding production and sale of an over-the-counter drug that is "different from or in addition to, or that is otherwise not identical with, a requirement under [federal law]." For that reason, Plaintiffs claim that Walgreens have an obligation to warn them about the risk of benzene exposure is preempted by the FDCA.

Conclusion

Therefore, Walgreens' motion to dismiss [14] is granted and Plaintiffs' complaint is dismissed without prejudice. Plaintiffs are granted leave to file an amended complaint by 6/20/2025. If Plaintiffs do not file an amended complaint by 6/20/2025, their complaint will be dismissed with prejudice. Plaintiffs should inform Walgreens and the Court's Deputy by email no later than 5/28/2025 whether they intend to file an amended complaint.

ENTERED:

Thomas M Durkin

Honorable Thomas M. Durkin
United States District Judge

Dated: May 20, 2025